Claims

1. A controlled release oral pharmaceutical preparation suitable for dosing every 24 hours comprising a substrate comprising a pharmaceutically effective amount of tramadol or a salt thereof and a pharmaceutically effective amount of topiramate; said preparation having a dissolution rate in vitro when measured using the Ph. Eur. Paddle Method at 75 rpm in 900 ml 0.05 M phosphate buffer at 37° C and using HPLC :
between 15 and 35% tramadol released after 1 hour;
between 28 and 48% tramadol released after 2 hours;
between 47 and 67% tramadol released after 4 hours;
between 68 and 88% tramadol released after 8 hours;
between 79 and 99% tramadol released after 12 hours;
between 86 and 105% tramadol released after 18 hours;
about 100% tramadol released after 24 hours; by weight,
said preparation providing a therapeutic effect for about 24 hours after oral administration.

2. An oral pharmaceutical preparation as in claim 1, said preparation having a dissolution rate as follows :
between 20 and 30% tramadol released after 1 hour;
between 33 and 43% tramadol released after 2 hours;
between 52 and 62% tramadol released after 4 hours;
between 73 and 83% tramadol released after 8 hours;
between 84 and 94% tramadol released after 12 hours;
between 91 and 100% tramadol released after 18 hours;
about 100% tramadol released after 24 hours; by weight.

3. An oral pharmaceutical preparation as in claim 1, said preparation having a dissolution rate as follows :
25% tramadol released after 1 hour;
38% tramadol released after 2 hours;
57% tramadol released after 4 hours;

78% tramadol released after 8 hours;
89% tramadol released after 12 hours;
95,5% tramadol released after 18 hours;
about 100% tramadol released after 24 hours; by weight.

4. An oral pharmaceutical preparation according to claims 1-3 wherein the tramadol salt is tramadol hydrochloride.

5. An oral pharmaceutical preparation according to claims 1-4, wherein said substrate is a suitable matrix material in which tramadol or its salt form is incorporated.

6. An oral pharmaceutical preparation according to claim 5 wherein thematrix material is xanthan gum.

7. An oral pharmaceutical preparation according to claims 1-6, wherein the preparation comprises two or more phases.

8. An oral pharmaceutical preparation according to claims 1-7 wherein the major part of the tramadol or its salt form and of the topiramate are in different phases of the said pharmaceutical preparation.

9. An oral pharmaceutical preparation according to claims 1-7 wherein the tramadol or its salt form and the topiramate are in different phases of the said pharmaceutical preparation.

10. An oral pharmaceutical preparation according to claims 1-9 wherein at least one phase contains the major part of tramadol or a salt thereof and at least another phase contains the major part of topiramate.

11. An oral pharmaceutical preparation according to claims 7-10 wherein the phases take the form of layers and at least one layer contains tramadol or a salt thereof and at least another layer contains topiramate.

12. An oral pharmaceutical preparation according to claims 1-11, which has two layers, one layer containing topiramate and another layer containing tramadol or a salt thereof.

13. An oral pharmaceutical preparation according to claims 1-11 which has three layers, one layer containing topiramate, another layer containing tramadol or a salt thereof, and a third isolator layer in between the tramadol and the topiramate layers.

14. An oral pharmaceutical preparation according to claims 7-10 wherein at least one of the phases take the form of pellets.

15. An oral pharmaceutical preparation according to claim 14 wherein all phases take the form of pellets.

16. An oral pharmaceutical preparation according to claims 14 wherein the pellets contain either tramadol or a salt thereof or topiramate.

17. A process for manufacturing an oral pharmaceutical preparation as claimed in claims 1-16 comprising mixing tramadol hydrochloride and topiramate with a suitable substrate.